



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/32, 25/06	A1	(11) International Publication Number: WO 93/01851 (43) International Publication Date: 4 February 1993 (04.02.93)
--	----	---

(21) International Application Number: PCT/GB92/01192

(22) International Filing Date: 2 July 1992 (02.07.92)

(30) Priority data:

9115533.3	18 July 1991 (18.07.91)	GB
9121710.9	12 October 1991 (12.10.91)	GB

(71) Applicant (for all designated States except JP KR US): STERIMATIC HOLDINGS LIMITED [-/GB]; Abnash Barn, Chalford Hill, Stroud, Gloucestershire GL6 8QN (GB).

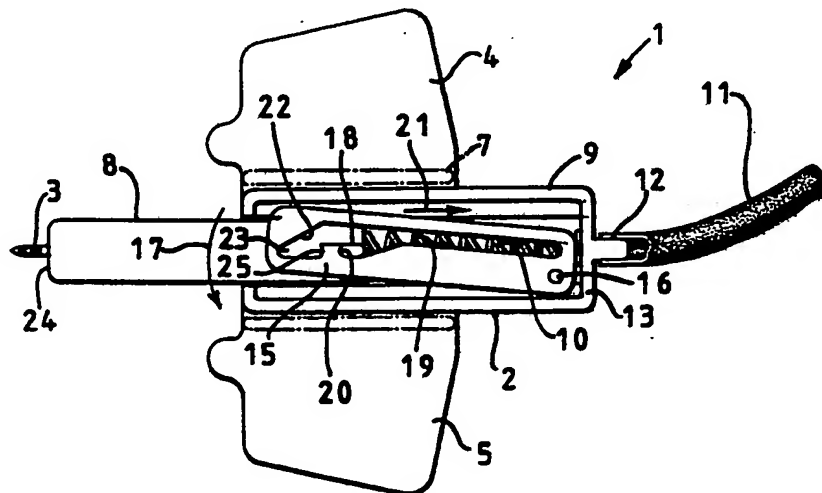
(71)(72) Applicant and Inventor (for JP KR US only): WOZENCROFT, Robert, Michael [GB/GB]; Flat 2, The Birches, Birches Drive, Stroud, Gloucestershire GL5, 1SF (GB).

(74) Agent: A.R. DAVIES &amp; CO.; 27 Imperial Square, Cheltenham, Gloucestershire GL50 1RQ (GB).

(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published  
With international search report.

(54) Title: SKIN PUNCTURING INSTRUMENTS, ESPECIALLY CLINICAL NEEDLES



## (57) Abstract

A butterfly needle accessory (1) comprises a protective guard (2) for a needle (3) and flexible wings (4 and 5) which may be attached to the patient's skin with adhesive tape. The guard (2) has two parts (8 and 9) movable relative to one another from a contracted position, in which the point of the needle projects from the guard, to an extended position, in which the point of the needle is shielded by the guard. The parts (8 and 9) are guided by a projection (18) on the part (8) engaging within a slot (19) in a latching member (15) within the part (9), and are biased into the extended position by a spring (10). The latching member (15) is pivotable transversely of the needle from an unlatching position, permitting movement of the projection along the track during contraction of the guard, to a latching position, for retaining the guard in the extended position shielding the point of the needle by engagement of the projection (18) with a shoulder portion (25) of the slot (19). A similar arrangement is applicable to a needle fitment for a syringe. Such arrangements are particularly advantageous in guarding against needle stick.

Best Available Copy

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark	MG	Madagascar		
ES	Spain				

-1-

## SKIN PUNCTURING INSTRUMENTS, ESPECIALLY CLINICAL NEEDLES

This invention relates to skin-puncturing instruments, such as syringes and needle fitments therefor and other types of clinical needle, such as so-called  
5 butterfly and fistula needles, for example.

After use of a skin-puncturing instrument to perform an injection or take up a sample of blood from a patient, for example, there is a risk that doctors or nurses will accidentally prick themselves with the needle  
10 of the syringe. This phenomenon is known as "needle stick" and can be highly dangerous due to the risk of transfer of blood-related diseases.

A skin-puncturing instrument is known of the type which includes a protective guard for surrounding a  
15 needle of the instrument and having two guard parts which are movable relative to one another from a contracted position, in which the needle projects beyond the guard to an extent to enable a skin-puncturing operation to be carried out, to an extended position, in which the point  
20 of the needle is shielded by the guard, wherein the two guard parts are guided relative to one another by a projection on one guard part engaging a track on the other guard part, and wherein a retaining shoulder portion of the track is provided for retaining the guard in the  
25 extended position. Such an instrument will be referred to hereinafter as "a skin-puncturing instrument of the type referred to".

European Patent Specifications Nos. 0268445A and

-2-

0367398A disclose skin-puncturing instruments of the type referred to which in addition include a compression spring acting to bias the guard into the extended position shielding the point of the needle. One of the prior  
5 arrangements disclosed incorporates retaining means for retaining the guard in the extended position which may be released from its locking position by manually rotating the guard. However it is an undesirable feature of such an arrangement that a twisting motion tends to be imparted  
10 to the end of the guard during a skin-puncturing operation, and that, under certain circumstances, the guard may not be automatically locked in its extended position after use. There are also a number of applications in which the prior arrangements are  
15 unsuitable for use, for example because they are too bulky and/or because they do not permit the point of the needle to be re-exposed after the guard has assumed its extended position.

It is an object of the invention to provide a  
20 skin-puncturing instrument of the type referred to possessing certain advantages over these prior arrangements.

The invention is defined by the accompanying claims.

25 The invention also provides a protective guard for surrounding a needle of a skin-puncturing instrument and having two guard parts which are movable relative to one another in the direction of the needle between a

contracted position, in which the point of the needle projects from the guard, and an extended position, in which the point of the needle is shielded by the guard, wherein retaining means are provided for retaining the guard in the extended position and for permitting movement of the guard into the contracted position only when an actuating part is manually held in an unlatching position.

In order that the invention may be more fully understood, preferred embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a view from above of a butterfly needle accessory according to the invention, with a cover removed;

Figure 2 is an axial section through the butterfly needle accessory of Figure 1;

Figure 3 is a view from above of a needle fitment for a syringe according to the invention, with a cover removed;

Figure 4 is an axial section through the needle fitment of Figure 3;

Figures 5 and 6 show the needle fitment of Figures 3 and 4 in two operating conditions;

Figure 7 is an axial section through a further needle fitment for a syringe according to the invention in the extended position;

Figures 8, 9 and 10 are partly exploded side views of the needle fitment of Figure 7 in the vicinity of

a collar, respectively in the extended position, in a partially contracted position and in a fully contracted position; and

Figures 11 and 12 show parts of two variants of  
5 the needle fitment of Figure 7.

Referring to Figures 1 and 2, the butterfly  
needle accessory 1 shown comprises a protective guard 2  
for a hollow pointed needle 3, and flexible wings 4 and 5  
connected to the guard 2 so as to be capable of being  
10 hinged from the position shown in broken lines 7 in  
Figures 1 and 2 to a flat position shown in Figure 1 in  
which adhesive tape may be used to secure the wings 4, 5  
to the patient's skin in known manner. An infusion tube  
11 is connected to a connector 12, to which the needle 3  
15 is also connected, for the purpose of supplying infusion  
fluid, such as an anaesthetic fluid, to the needle 3.

The guard 2 has an inner guard part 8 which may  
be telescoped within an outer guard part 9 against the  
action of a compression spring 10. The outer guard part 9  
20 comprises a base 13 through which the needle 3 extends and  
within which the compression spring 10 is accommodated so  
as to surround the needle 3, and a cover 14 (which has  
been removed in Figure 1) connected to the base 13 as by  
sonic welding. A latching member 15 is mounted within the  
25 outer guard part 9 by a pivot pin 16 so that its end  
remote from the pivot pin 16 is movable transversely of  
the needle 3 as indicated by the arrow 17 in Figure 1.  
Furthermore a projection 18 on the inner guard part 8

engages within an axially extending slot 19 in the latching member 15 and acts to control relative movement between the guard parts 8 and 9 in a manner which will be described below with reference to the operation of the  
5 accessory.

When the accessory is initially supplied for use the relative positions of the guard parts 8 and 9 are as shown in Figures 1 and 2, although the projecting point of the needle 3 is generally shielded by a removable cap (not  
10 shown) which is an interference fit on the end of the inner guard part 8. After removal of the cap the point of the needle 3 is exposed to a sufficient extent to enable it to be positioned at the intended skin-puncturing site, the inner guard part 8 being retained in this partially  
15 contracted position by engagement of the projection 18 with a shoulder portion 20 of the slot 19 (and by the action of the spring 10 tending to force the inner guard part 8 outwardly of the outer guard part 9).

Pressure is then applied to the accessory in  
20 order to puncture the patient's skin and locate the point of the needle 3 in the required position in a vein, the counter pressure applied to the end of the inner guard part 8 by the patient's skin causing telescoping of the inner guard part 8 within the outer guard part 9 so that  
25 the projection 18 moves away from the shoulder portion 20 and along the slot 19 in the direction of the arrow 21 in Figure 1. This simultaneously results in pivoting of the latching member 15 in the direction of the arrow 17

-6-

against the resilient bias exerted by the spring 10 due to the lateral offset of the spring axis with respect to the pivot pin 16. With the point of the needle 3 suitably located within a vein, the accessory may then be taped to the patient's skin as described, and infusion fluid may be supplied along the needle 3.

After use the accessory may be un-taped and the needle 3 withdrawn from the patient resulting in movement of the inner guard part 8 outwardly of the outer guard part 9 under spring pressure, this in turn resulting in movement of the projection 18 in the opposite direction along the slot 19 until it contacts a ramp surface 22 of the slot 19 which guides the projection 18 into an end portion 23 of the slot 19 within which it is retained by the action of the spring 10. When the projection 18 is within the end portion 23, an end part 24 of the inner guard part 8 extends over the point of the needle 3, as shown by the broken lines 24' in Figure 2, thereby shielding the point of the needle. Furthermore application of pressure to the end part 24 in the direction of contracting movement will result in the projection 18 engaging a shoulder portion 25 within the slot 19 which will prevent the point of the needle 3 from being re-exposed by further movement of the inner guard part 8 inwardly of the outer guard part 9. Thus the guard 2 is locked in its extended position in which it effectively guards against needle stick after removal of the accessory from the patient.



-7-

There will now be described with reference to Figures 3 and 4 a needle fitment 30 comprising a protective guard 31 for a needle 32 connectible to the outlet of a syringe (not shown) by a connector 33 in  
5 known manner.

The guard 31 has an inner, tubular guard part 34 which may be telescoped within an outer guard part 35 against the action of a compression spring 36. The outer guard part 35 has a base 37 and a cover 38 (which is shown  
10 removed in Figure 3) connected to the base 37. A latching member 39 is pivotally mounted within the outer guard part 35 by a pivot pin 40 and has an actuating part 41 which extends through an aperture 42 in the outer guard part 35. A projection 43 on the inner guard part 34 engages within  
15 an axially extending slot 44 in the latching member 39, and, when the fitment is initially supplied for use, the guard parts 34 and 35 are in the relative positions shown in Figures 3 and 4 in which the inner guard part 34 shields the point of the needle 32 and in which the  
20 projection 43 is within an end portion 45 of the slot 44 within which it is retained by spring pressure.

The manner of use of the fitment 30 will be appreciated by reference to Figures 5 and 6 which show the fitment 30 attached to a syringe 50 in the hand 51 of a  
25 user. Initially, when the needle 32 is to be located at the intended site of injection, the actuating part 41 of the latching member 39 is depressed by the user's thumb, as indicated by the arrow 52 in Figure 5, to move the

projection 43 out of the end portion 45 of the slot 44 and to expose the point of the needle 32. When the point of the needle 32 has been applied to the patient's skin, pressure is exerted in the direction of the arrow 53 in Figure 5 to cause the needle 32 to enter the patient and the inner guard part 34 to be retracted within the outer guard part 35, the projection 43 travelling along the slot 44. When the injection has been performed and the needle 32 is withdrawn from the patient, the inner guard part 34 is moved outwardly of the outer guard part 35 under spring pressure, and the actuating part 41 of the latching member 39 is released by the user's thumb, as indicated by the arrow 54 in Figure 6, so as to cause the projection 43 to re-enter the end portion 45 of the slot 44. This automatically locks the guard 31 in the extended position shielding the point of the needle 32 by virtue of the fact that pressure exerted on the end of the inner guard part 34 in the direction of the arrow 55 will simply cause the projection 43 to engage a shoulder portion 56 (see Figure 3) of the slot 44 which will prevent further retraction of the inner guard part 34 as long as the actuating part 41 of the latching member 39 is not depressed.

The above described needle fitment 30 is particularly advantageous as it enables the point of the needle to be exposed as many times as required by depression of the actuating part of the latching member, whilst providing reliable protection against needle stick

by virtue of the fact that the guard will always assume its extended position shown in Figure 6 when the actuating part of the latching member is released.

There will now be described with reference to  
5 Figure 7 an alternative form of needle fitment 100 comprising a protective guard 101 forming an integral assembly with a hollow pointed needle 102. The guard 101 consists of an inner sleeve 103 having a tapered end portion 104 and an outer sleeve 105. The outer sleeve 105  
10 incorporates a latching member in the form of a collar 106 which is a snap fit within an annular recess 107 in the inside surface of the outer sleeve 105 by virtue of an annular rib 106A on the collar engaging within an annular groove 107A in the recess. Furthermore the outer sleeve  
15 105 is provided with a connector 109 through which the needle 102 extends and by means of which the guard 101 is attached to the outlet of a syringe (not shown).

A compression spring 108 is accommodated within the outer sleeve 105 and acts between the connector 109  
20 and a shoulder 110 on the inside surface of the inner sleeve 103. The inner and outer sleeves 103 and 105 are fitted together so that the inner sleeve 103 is capable of being telescoped within the outer sleeve 105 against the action of the spring 108 in order to enable the point of  
25 the needle 102 to project through an aperture 111 at the end of the inner sleeve 103 to an extent to permit an injection to be effected, but so that the inner sleeve 103 is automatically moved into the extended position to

-10-

shield the point of the needle 102 when the injection has been carried out.

The inner sleeve 103 is retained in engagement with the outer sleeve 105 when in its extended position by an annular shoulder 112 on the outside of the inner sleeve 103 bearing against an annular shoulder 113 on the inside of the collar 106. Furthermore the outside surface of the inner sleeve part has an outwardly extending projection 114 (shown in broken lines) which engages within a track 115 (shown in broken lines) on the inside surface of the outer sleeve 105 including the collar 106. The track 115 is formed by a slot 116 extending through the wall of the collar 106, and a longitudinally extending groove 117 on the inside surface of the outer sleeve 105, the projection 114 extending through the slot 116 and engaging in the groove 117 in order to ensure that there is no relative rotation between the inner and outer sleeves 103 and 105 during contraction of the guard which might result in jamming of the sleeves 103 and 105 due to the fact that such twisting movement will tend to be resisted by frictional engagement of the end of the guard with the skin of the patient.

The collar 106 is capable of limited rotation within the recess 107 in the outer sleeve 105, and is provided with an actuating portion in the form of a milled ring 118 which is capable of being manually rotated through a limited angle when the guard is in its extended position in order to unlock the guard. The precise

-11-

manner in which such unlocking is effected will now be described with reference to Figures 8, 9 and 10 which show side views of the collar 106 in three operational states of the fitment, the collar 106 being shown withdrawn from the outer sleeve 105 in order to render the operation easier to understand.

It will be appreciated that the slot 116 has a linear portion 119 and a hooked portion 120 within which the projection 114 is held to retain the guard in the extended position when the collar 106 is in the locking position, as shown in Figure 8. The guard may be supplied in this position in which the needle 102 is shielded by the inner sleeve 103 and cannot be accidentally exposed by applying pressure to the end of the inner sleeve 103 in the direction of contracting movement since such pressure will cause the projection 114 to engage a shoulder portion 120A.

When it is desired to perform an injection the milled ring 118 is turned anti-clockwise to cause the projection 114 to move out of the hooked portion 120 into a temporary retaining portion 121 of the slot 116, as shown in Figure 9. This results in the inner sleeve 103 being slightly retracted within the outer sleeve 105 so that the guard is placed in a partially contracted position in which it is held by engagement of the projection 114 with a further shoulder portion 121A and in which the point of the needle 102 projects from the guard to the extent necessary to enable the point of the needle

-12-

to be located at the intended site of injection.

After the point of the needle has been correctly located pressure is exerted on the syringe to cause the point of the needle to puncture the patient's skin and to cause the inner sleeve 103 to telescope within the outer sleeve 105 due to the counter pressure exerted on the end of the inner sleeve 103 by contact with the patient's skin. Such telescoping movement is not resisted by the collar 106 since the projection 114 engages a guide portion 122 of the slot 116 which causes the collar 106 to rotate clockwise into the position shown in Figure 10 in which the linear portion 119 of the slot 116 is aligned with the groove 117 in the inside surface of the outer sleeve 105, thus enabling the projection 114 to move along the linear portion 119 as shown.

When the guard has been sufficiently contracted to enable the needle to enter the injection site to the required depth, a suitable dose may be delivered to the injection site through the needle, and the needle may be subsequently withdrawn from the injection site. As the needle is withdrawn, it will be appreciated that the guard will be gradually returned to its extended position under the action of the spring 108 with the projection 114 travelling back along the linear portion 119 of the slot 116 until it contacts a further guide portion 123 of the slot 116 which results in clockwise rotation of the collar 106 so as to cause the projection 114 to enter the hooked portion 120. Thus the guard is automatically returned to

-13-

the extended position and is locked therein by the projection 114 engaging in the hooked portion 120 of the slot 116, as shown in Figure 8. This safely shields the point of the needle without requiring any special manual measures to be taken to effect such locking, and permits safe disposal of the needle if required.

Alternatively, of course, if it is required to re-expose the needle, the milled ring 118 may be again rotated to unlock the guard and permit the inner sleeve 103 to be telescoped within the outer sleeve 105 as previously described.

Figure 11 shows the collar 106 and inner sleeve 103 only of a variant of the needle fitment 100 just described in which the needle cannot be subsequently re-exposed after an injection has been effected and the guard has been locked in its final extended position. To this end the collar 106 has a slot 130 as shown having a first hooked portion 131 within which the projection 114 is initially held to retain the guard in the extended position, and a second hooked portion 132 within which the projection 114 is held to lock the guard in its extended position after an injection has been effected. In addition the slot 130 has a temporary retaining portion 133 with which the projection 114 is engaged when the milled ring 118 is turned to cause the projection 114 to move out of the hooked portion 131 in order to move the guard into a partially contracted position, as shown in Figure 11, to locate the needle at the intended site of

-14-

portion 119 of the slot 130 as previously described, but on return of the projection 114 along the linear portion 119 as the guard moves towards its extended position the projection 114 is automatically caused to enter the hooked portion 132 and to thereby permanently lock the guard in the extended position. The projection 114 cannot subsequently be moved out of the hooked portion 132 by rotation of the milled ring 118 because of the steepness of the inclined surface 134.

10           Figure 12 shows the collar 106' and the inner sleeve 103 of a further variant which does not include a milled ring permitting manual rotation of the collar and in which the guard is permanently locked in its extended position after use. In this case the slot 130' has a  
15 retaining portion 140 within which the projection 114 is held prior to use to retain the guard in a partially contracted position in which the point of the needle 102 projects from the guard to an extent necessary to enable the point of the needle to be located at the intended site  
20 of injection, as shown in Figure 12. A protective cap (not shown) will be provided on the end of the inner sleeve 103 to shield the tip of the needle, this cap only being removed immediately prior to the injection being effected. After the injection has been effected and on  
25 return of the projection 114 along the linear portion 119 of the slot 130', the projection 114 is automatically caused to enter the hooked portion 141 to permanently lock the guard in the extended position shielding the point of



the needle.

In a further, non-illustrated variant the slot may include a temporary catch portion into which the projection may be moved, and/or from which the projection  
5 may be released, by manual rotation of the collar in order to temporarily retain the guard in a contracted position in which a substantially greater portion of the needle is exposed than in the partially contracted position.

The provision of the rotatable collar enables  
10 the guard to be automatically locked in its extended position shielding the point of the needle after use, and preferably also prior to use. Furthermore a twisting motion is not imparted to the end of the inner sleeve in use.

15 There are many applications of the skin-puncturing instruments described. For example, such an instrument may be used with a hollow needle as part of an injection or fluid collection device, such as a hypodermic syringe, a catheter placement unit or the like. In this  
20 case the guard may be formed as an integral part of the device, or alternatively it may be formed as an accessory which is attachable to, and possibly subsequently detachable from, such a device. The instrument may also  
25 be used with a needle which is not hollow, for example in a lancet device. In this case the needle may simply be supported on an inner part which is displaceable within an outer sleeve.

CLAIMS

1. A skin-puncturing instrument which includes a protective guard (2, 31, 101) for surrounding a needle (3, 32, 102) of the instrument and having two guard parts (8, 9, 34, 35, 103, 105) which are movable relative to one another from a contracted position, in which the needle projects beyond the guard to an extent to enable a skin-puncturing operation to be carried out, to an extended position, in which the point of the needle is shielded by the guard, wherein the two guard parts (8, 9, 34, 35, 103, 105) are guided relative to one another by a projection (18, 43, 114) on one guard part engaging a track (19, 44, 115) on the other guard part, and wherein a retaining shoulder portion (25, 56, 102A) of the track is provided for retaining the guard in the extended position, characterised in that one of the shoulder portion (25, 56, 120A) and the projection (18, 43, 114) is provided on a latching member (15, 39, 106) which is connected to one of the guard parts (8, 9, 34, 35, 103, 105) and which is movable relative to the guard parts from an unlatching position, permitting movement of the projection along the track during contraction of the guard, to a latching position, in which contraction of the guard from its extended position shielding the point of the needle is prevented by engagement of the shoulder portion by the projection.

2. An instrument according to Claim 1, characterised in that the latching member (15, 39) is

elongate and is pivoted at one end to permit movement of its opposite end transversely of the direction of the length of the needle to effect movement from the unlatching position to the latching position.

5 3. An instrument according to Claim 2, characterised in that the latching member (15, 39) extends generally in the direction of the length of the needle, and the track is in the form of a slot (19, 44) extending substantially in the direction of the length of  
10 the latching member, the shoulder portion (25, 56) being provided in the region of said opposite end of the latching member.

4. An instrument according to Claim 1, characterised in that the latching member comprises a  
15 collar (106) connected to one of the guard parts (105) and defining at least a part of the track (115), the collar (106) being rotatable with respect to the guard parts to effect movement from the unlatching position to the latching position.

20 5. An instrument according to Claim 4, characterised in that the track (115) is formed by a slot (116) extending through the wall of the collar (106) and a groove (117) in said one guard part (105), the projection (114) extending through the slot (116) and engaging in the  
25 groove (117).

6. An instrument according to Claim 4 or 5, characterised in that said one guard part is an outer sleeve (105) within which the other guard part in the form

-18-

of an inner sleeve (103) is telescopically engageable, and the collar (106) is fitted within an end portion of the outer sleeve (105).

7. An instrument according to any preceding claim, wherein the track (19, 44, 115) includes a further shoulder portion (20, 121A) with which the projection (18, 43, 114) engages to retain the guard in a partially contracted position in which the point of the needle projects beyond the guard only to an extent necessary to enable the point of the needle to be located at the intended skin-puncturing site.

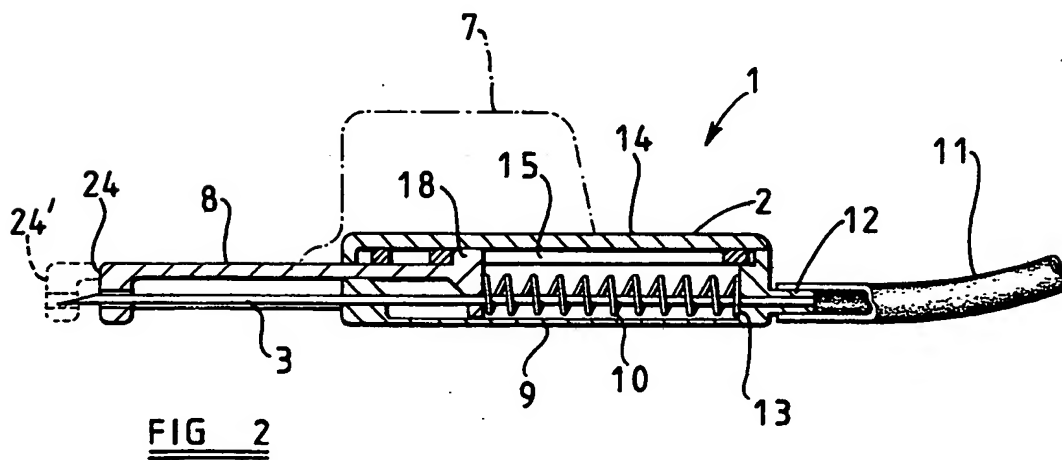
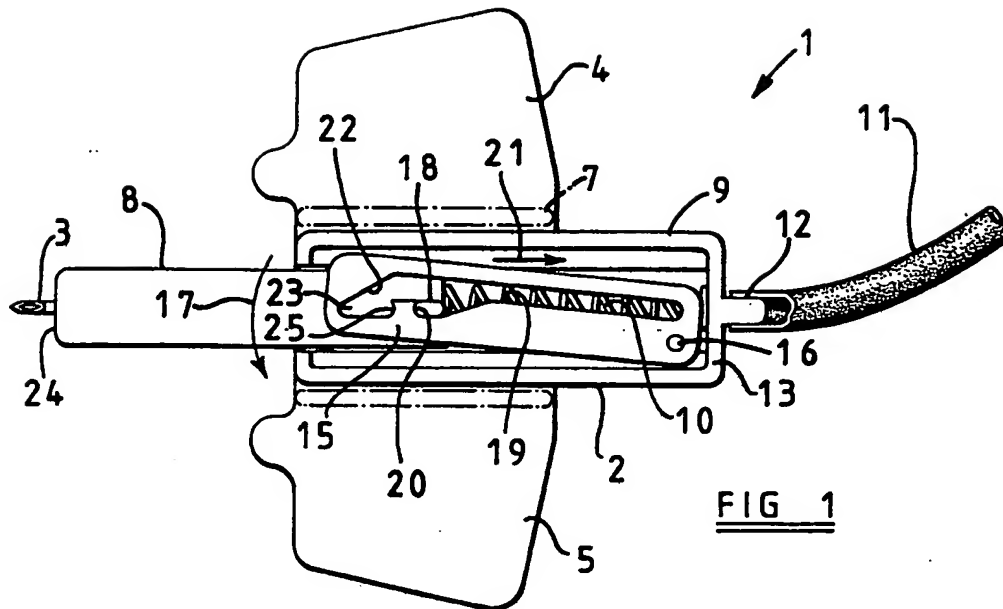
8. An instrument according to any preceding claim, wherein an actuating part (41, 118) of the latching member (39, 106) is manually actuatable to move the latching member from the latching position to the unlatching position to permit contraction of the guard in a skin-puncturing operation.

9. An instrument according to claim 8, characterised in that the latching member (15, 39) permits movement of the guard into the contracted position only when the actuating part is manually held in the unlatching position.

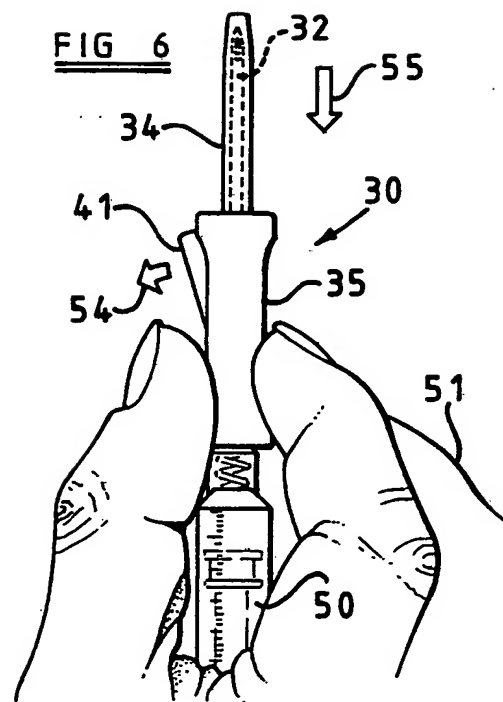
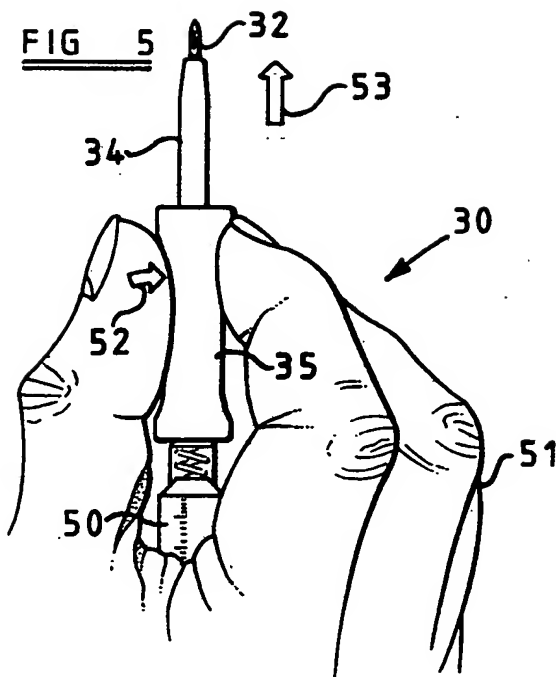
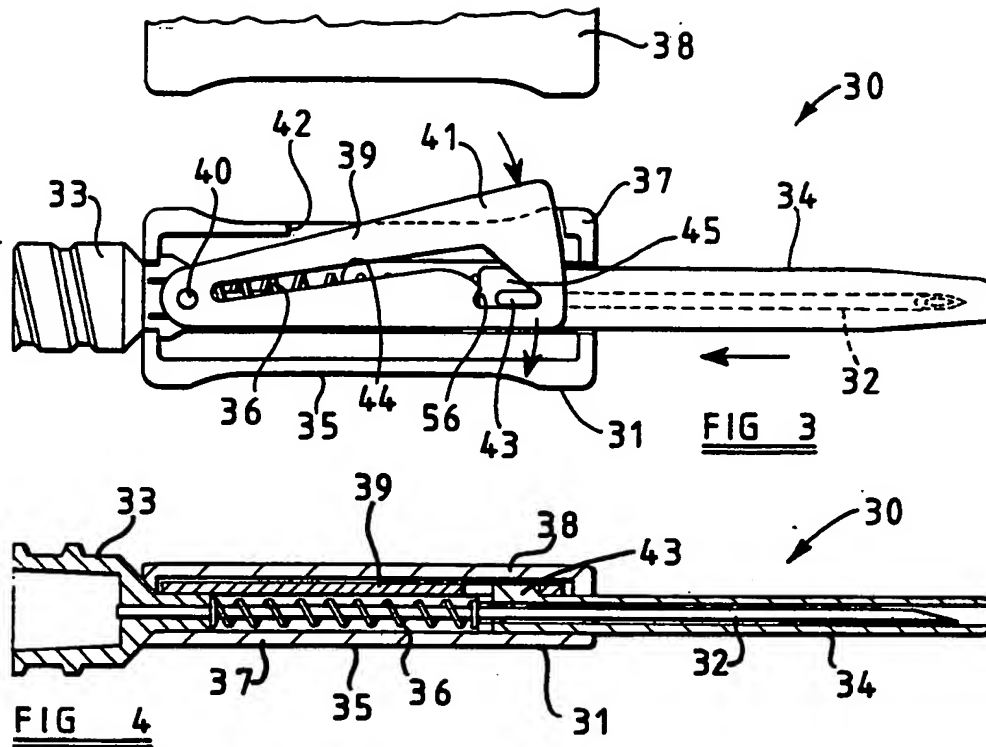
10. An instrument according to any preceding claim, characterised in that biasing means (10, 36, 108) are provided for biasing the guard towards its extended position so that the guard will automatically assume its extended position on release of pressure applied to the end of the guard in the direction of contracting movement

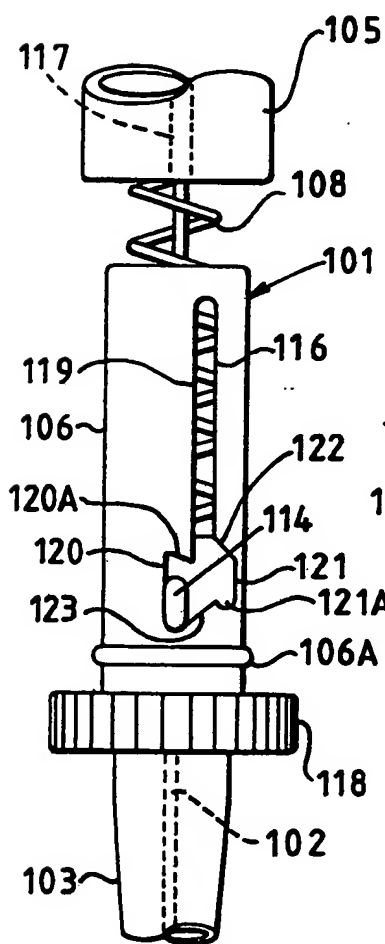
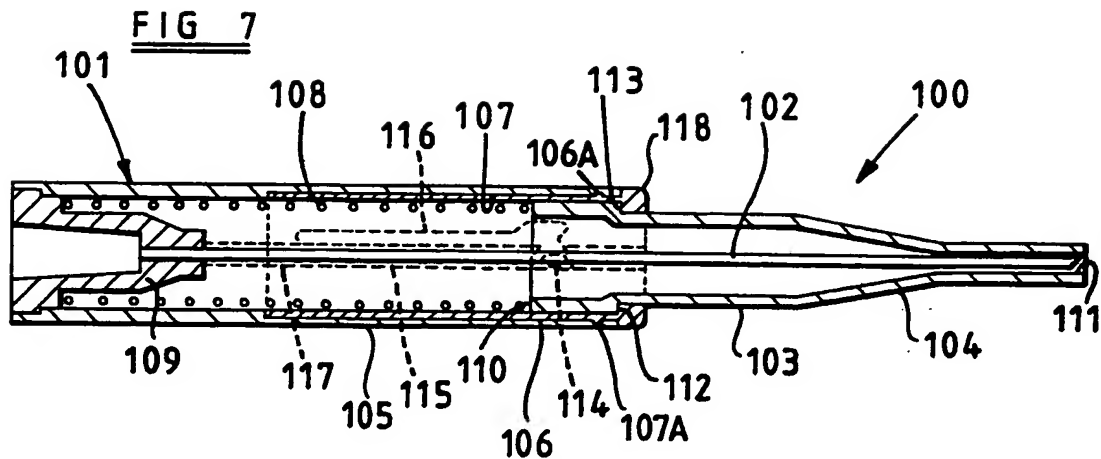
after a skin-puncturing operation has been carried out.

1 / 4

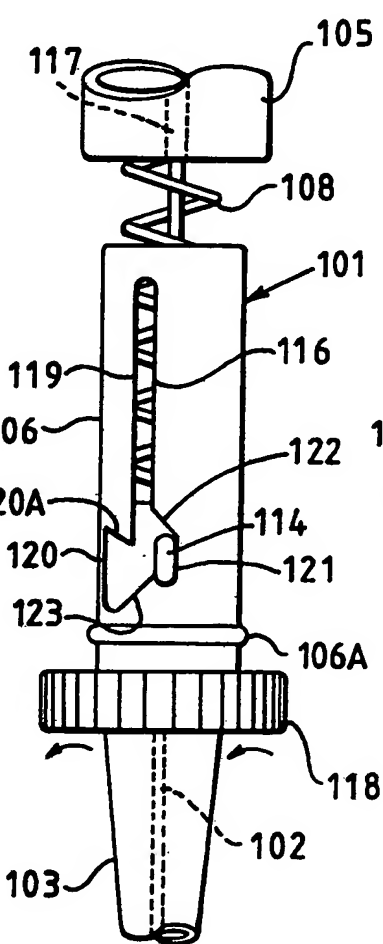


2 / 4

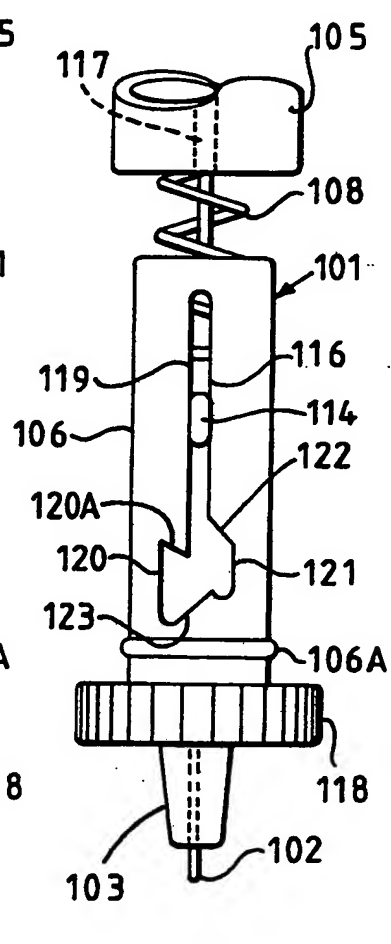




**FIG 8**

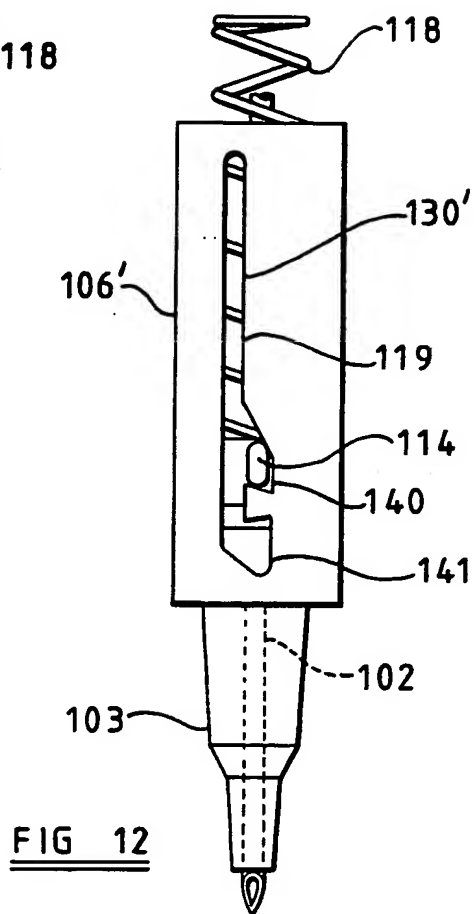
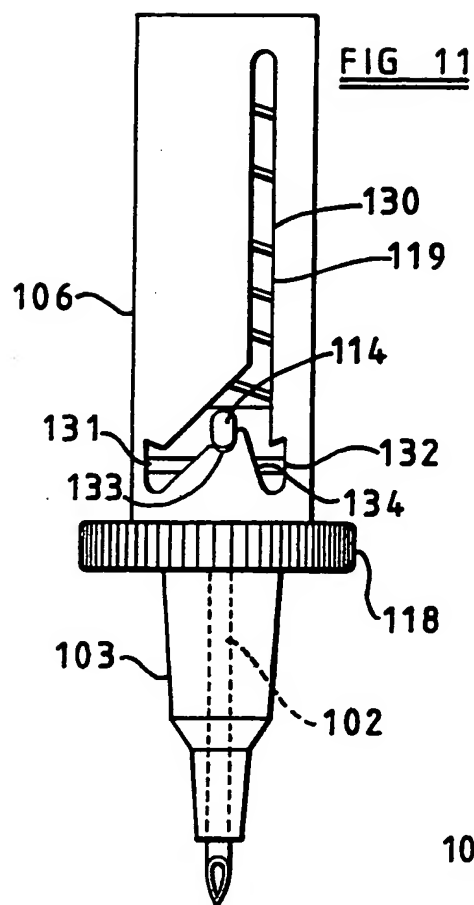


**FIG 9**



**FIG 10**





## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 92/01192

**I. CLASSIFICATION OF SUBJECT MATTER** (If several classification symbols apply, indicate all)<sup>6</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M5/32; A61M25/06

**II. FIELDS SEARCHED**Minimum Documentation Searched<sup>7</sup>

Classification System

Classification Symbols

Int.Cl. 5

A61M

Documentation Searched other than Minimum Documentation  
to the extent that such Documents are included in the Fields Searched<sup>8</sup>**III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup>**

Category <sup>9</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
Y	EP,A,0 268 445 (STERIMATIC HOLDINGS LIMITED) 25 May 1988 cited in the application see column 2, line 52 - column 3, line 54; figures 1-3	1
A		10
Y	US,A,4 795 432 (KARCZMER) 3 January 1989 see column 7, line 7 - line 12; figures 17,18	1
A		10
A	EP,A,0 367 398 (STERIMATIC HOLDINGS LIMITED) 9 May 1990 cited in the application see the whole document	1,4-7,10
	-/-	

<sup>10</sup> Special categories of cited documents:<sup>"A"</sup> document defining the general state of the art which is not considered to be of particular relevance<sup>"E"</sup> earlier document but published on or after the international filing date<sup>"L"</sup> document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<sup>"O"</sup> document referring to an oral disclosure, use, exhibition or other means<sup>"P"</sup> document published prior to the international filing date but later than the priority date claimed<sup>"T"</sup> later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<sup>"X"</sup> document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step<sup>"Y"</sup> document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art<sup>"A"</sup> document member of the same patent family**IV. CERTIFICATION**

Date of the Actual Completion of the International Search

06 OCTOBER 1992

Date of Mailing of this International Search Report

13. 10. 92

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

SEDY R.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,4 946 446 (VADHER) 7 August 1990 see column 2, line 42 - line 50 see column 3, line 1 - line 5; figures 1-3	1, 10

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO. GB 9201192  
SA 61398**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file as  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 06/10/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0268445	25-05-88	AU-A- 8076387	06-05-88
		AU-B- 601518	13-09-90
		AU-A- 8140687	26-05-88
		WO-A- 8802640	21-04-88
		JP-A- 63139564	11-06-88
		US-A- 4813940	21-03-89
US-A-4795432	03-01-89	None	
EP-A-0367398	09-05-90	AU-A- 4328689	01-05-90
		WO-A- 9003815	19-04-90
		JP-T- 4501672	26-03-92
		US-A- 5104384	14-04-92
US-A-4946446	07-08-90	GB-A- 2232602	19-12-90

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**